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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/347,845	09/30/1999	YI YANG	243/079	4401

7590

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EXAMINER

BUI, VY Q

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/347,845

Applicant(s)

YANG ET AL

Examiner

Vy Q. Bui

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/5/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-6,8-15 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-15 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/5/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 3-4, 8-15, 17-22 and 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by VON OEPEN (6,193,747).

As to claims 1, 3-4, 8-11, and 24-25, VON OEPEN (Fig. 8 and see column 1, lines 36-39, VON OEPEN) discloses a **non-sinusoidal** zigzag pattern tubular stent (60) expandable from a contracted condition for easy introduction of the stent into a body lumen (a blood vessel) to an enlarged condition for supporting and keeping the body lumen (the blood vessel) open. Inherently, the stent is biased from a contracted condition either by a balloon or by a self-expanding property of the stent material towards an enlarged condition (as recited in claims 4, 24-25) to support the body lumen. The stent comprises:

- **A central portion consists essentially of a series of cylindrical bands, each band comprises a generally non-sinusoidal zigzag pattern of diagonal elements having generally arcuate shapes, arbitrarily assigned either a clockwise or counter clockwise orientation (please, see Von Oepen's Fig. 8 reproduced on page 5).**

Art Unit: 3731

- A plurality of straight and short or long connectors (I-shaped labeled as elements 66, 67) extending substantially parallel to the longitudinal axis of the stent. Notice that in a contracted configuration during deployment of the stent, connectors 66, 67 are squeezed closed one to each other and connectors 66, 67 are substantially parallel to the longitudinal axis of the stent.
- The short longitudinal connectors have a longitudinal dimension substantially smaller than a longitudinal dimension of the diagonal elements (as recited in claim 9). The diagonal elements comprise 1st and 2nd generally straight portions having 1st ends connected to preceding and succeeding diagonal elements and 2nd ends being connected together (as recited in claim 10).
- The diagonal elements of each cylindrical band are out of phase with any adjacent cylindrical band (as recited in claim 11).

As to claims 12-15 and 17-22, VON OEPEN (Fig. 8 as reproduced and shown on page 5 of this paper; see column 1, lines 36-39, VON OEPEN) discloses a tubular stent (60) comprising:

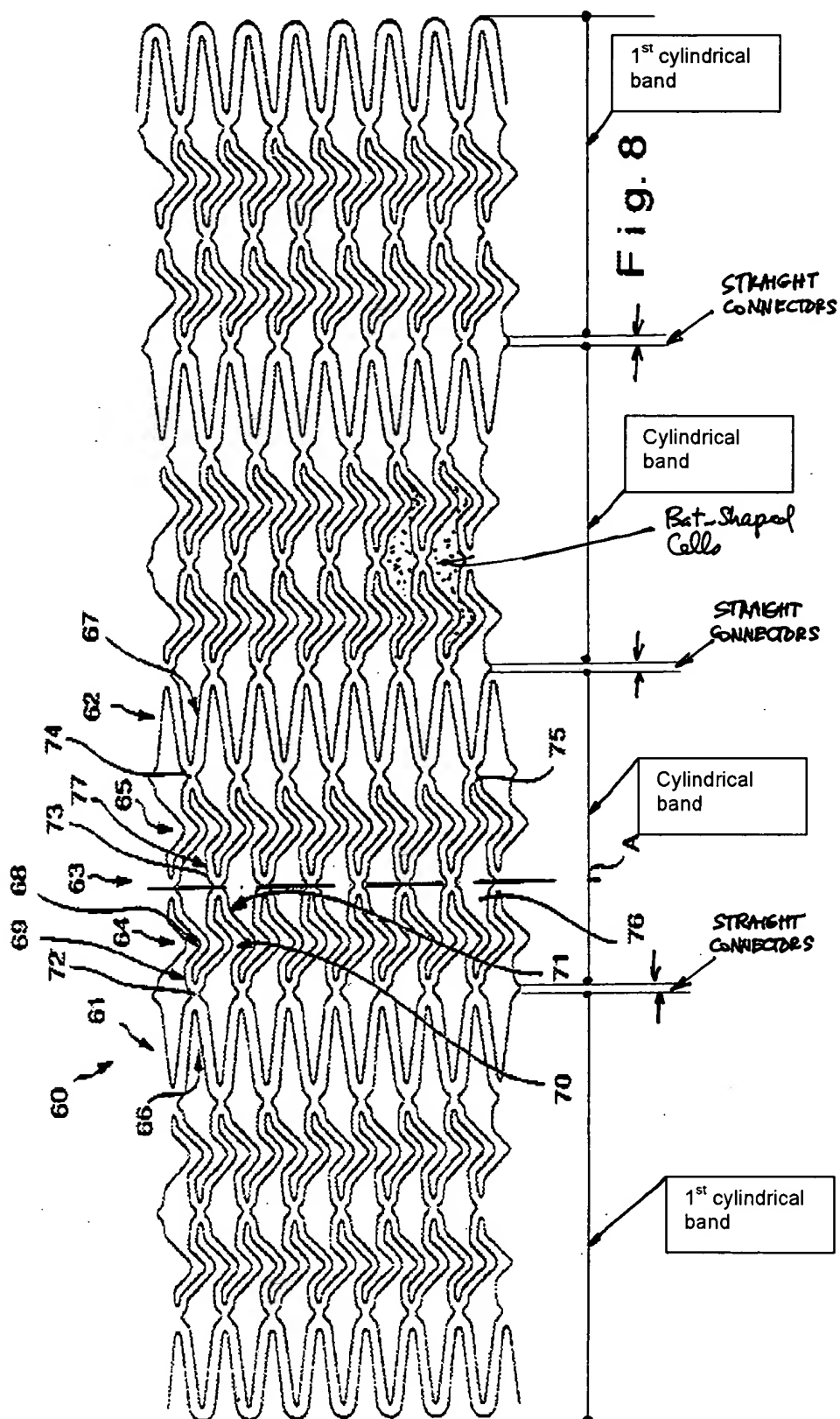
- A central portion consist essentially of a plurality of bat-shaped cells formed from **non-sinusoidal** cylindrical bands each cell having a head region, a tail region and opposing curved wing regions. The central portion consists essentially of a plurality of bat-shaped cells because there are a majority of bat-shaped cells in the central portion.
- A plurality of **straight short and long** connectors (I-shaped) extending substantially parallel to a longitudinal axis (as recited in claims 12 and 15) and **connecting each of the adjacent cells**. Notice that in a contracted configuration during deployment of the

Art Unit: 3731

stent along a blood vessel, connectors 66, 67 are squeezed closed one to each other and connectors 66, 67 are substantially parallel to the longitudinal axis of the stent.

- The head and tail regions are aligned about the circumference of the stent, the wing regions have a generally V-shaped extending longitudinally away from the head and tail regions (as recited in claim 13).
- The cells are arranged sequentially about the circumference, thereby defining a cylindrical band (as recited in claim 14).
- The wing regions are defined by 1st and 2nd arcuate members, the 1st and 2nd arcuate members comprising a pair of generally straight portions connected to one another by a curved portion, and the curved portion defines an apex of the "V" shape curved wing regions, the apices all pointing substantially in a single direction (as recited in claims 17-18).
- The head regions and tail regions are defined by longitudinal connectors (I-shaped connectors), one of the straight portions of each of the first and second arcuate members is substantially shorter than the other generally straight portion of the respective arcuate member, and the longitudinal connectors define the tail region also define the head region of an adjacent cell (as recited in claims 19-21).
- The connectors comprise a longitudinal connector (V-shaped connector) extending between a wing region of a first cell and a wing region of an adjacent cell (as recited in claim 22).

Art Unit: 3731



Art Unit: 3731

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over VON OEPEN (6,193,747) in view of STEINKE (6,224,626).

As to claims 2 and 23, VON OEPEN discloses substantially all structural limitations as recited in the claims, except for the stent 60 is not a coiled-sheet stent. STEINKE (column 2, lines 15-19; claim 6) discloses a coiled sheet stent of a shape memory material such as Nitinol having a variable expanded diameter to better fit inside a blood vessel over a tubular stent, which can better fit in a blood vessel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make VON OEPEN stent 60 a coiled-sheet stent as claimed as this configuration would provide a stent with variable expanded diameter to better fit inside a blood vessel.

3. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over VON OEPEN (6,193,747) in view of STEINKE (6,224,626) and further in view of KHOSRAVI et al (5,824,054).

As to claims 5-6, VON OEPEN (Figs. 8-9, 4-6) discloses substantially all structural limitations as recited in the claims, including ends of adjacent diagonal are expanded further away from one another in a stretched condition than in an unstretched condition. VON OEPEN and STEINKE do not disclose the stent made of a shape memory alloy having a transition temperature below the body temperature. However, KHOSRAVI (column 5, lines 59-63) discloses a coiled sheet stent made of a shape memory alloy having a transition temperature below body temperature. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the VON OEPEN stent a coiled-sheet stent of a shape memory alloy having a transition temperature below body temperature as taught by KHOSRAVI, as this modification would allow the stent to be expanded by the body temperature of a patient when deployed.

Art Unit: 3731

Response to Amendment

The claims as filed in the amendment on 4/08/2004 under 37 CFR 1.131 have been carefully considered. However, the claims are still read on Fig. 8 of Von Oepen-'747 as indicated in the above rejection.

Conclusion


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



07/18/2005

Vy Q. Bui
Primary Examiner
Art Unit 3731